REMARKS

I. Statement

Examiner Blessing Fubara, and Applicant's representatives, Pierre Kary, Robin Teskin, and Victoria A. Silcott, attended a telephonic Examiner interview held on March 7, 2007. Applicant thanks Examiner Fubara for her time and attention.

During the interview, four proposed claim amendments of pending independent claim 9 were discussed. Examiner Fubara stated that the claims, as amended, would overcome the rejections under 35 U.S.C. § 112, first paragraph, because the claims recited "urethra" and therefore, are enabling. In addition, because the proposed claims are supported by the original specification, the claims also do not introduce new matter.

II. Amendment to the Claims

Upon entry of the foregoing amendment, claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80, and 82-90 will be pending. Claims 9-17, 29-32, 34-38, 52-55, 57, 62, 63, 67-69, and 78-84 stand rejected. Claims 54, 55, 57, 63, and 81 have been cancelled without prejudice. Applicant reserves all rights to pursue protection for the subject matter of all cancelled claims in future patent applications. Claims 9-15, 17, 29-32, 34-36, 52, 53, 62, 67-69, 78-80, and 82-84 are amended. New claims 85-90 are added.

Applicant respectfully requests entry of the above Amendment and submits that the Amendment does not introduce new matter. Support for the amendment to the claims and for new claims can be found throughout the specification (considered as a whole) and in the claims as originally filed. In particular, support for the amendment to claim 9 can be found, *inter alia*, in the specification at page 2, lines 1-2; page 4, lines 1-3; and page 8, lines 24-26. Claims 10-15, 17, 29-32, 34-36, 52, 53, 55, 62, 67-69, and 82-84 have been amended for proper dependency. Support for further amendments to claims 14, 62, and 82-84 can be found, *inter alia*, in the specification at page 6, lines 20-23. Support for the amendment to claim 78 can be found, *inter alia*, in the specification at page 8, lines 30-32. Support for the amendment to claim 79 can be found, *inter alia*, in the specification at page 2, lines 1-3 and page 4, lines 24-25. Support for the amendment to claim 80 and for new claim 85 can be found, *inter alia*, in the specification at page 9, lines 1-2. Support for new claim 86 can be found, *inter alia*, in the specification at page 11, line 15. Support for new claim 87 can be found, *inter alia*, in the specification at page 4, lines

12-22. Support for new claim 88 can be found, *inter alia*, in the specification at page 5, lines 21-23 and 32-33. Support for new claim 89 can be found, *inter alia*, in the specification at page 7, lines 5-8. Support for new claim 90 can be found, *inter alia*, in the specification at page 4, lines 30-34; page 5, lines 4-7, 17-19 and 28-30; page 6, lines 20-23; and page 7, lines 5-8.

Based on the above amendments, Applicant respectfully submits that the claims are in condition for allowance. Applicant respectfully requests reconsideration of the rejections and that the claims be passed to issue.

III. Rejection Under 35 U.S.C. § 112

A. First Paragraph (Written Description)

Claims 14, 54, 57, 62, 63, 79, and 81-84 were rejected for failing to comply with the written description requirement. *See* Office Action, p. 3. The Office Action alleged that the recitation of generic water and aqueous solution introduced new matter into the claims because the specification discloses pyrogen-free water and saline solution. *See id.*

Claims 14, 62, 79, and 82-84 have been amended to specify "pyrogen-free" water and "saline" solution. Claims 54, 57, 63, and 81 have been cancelled. Therefore, the rejection has either been rendered moot or accommodated. For at least these reasons, Applicant respectfully requests that the rejection be reconsidered and withdrawn.

B. First Paragraph (Enablement)

Claims 10-17, 29-38, 52-55, 57, 62[1], 63, 67-69, 78, and 79 were rejected for failing to provide sufficient enablement for all canals/channels that are conduits. *See* Office Action, pp. 3-6.

Independent claims 9, 78-80, and 85, from which all other pending claims depend, have been amended to recite "urethra" or "urethral" (claim 79). As acknowledged by the Examiner in the telephonic interview held on March 7, 2007 (see Section I), the amended claims are enabling and do not introduce new matter. For at least these reasons, Applicant respectfully requests that the rejection be reconsidered and withdrawn.

[1] Although the Office Action lists claim 63 twice, Applicant assumes the Office Action meant to list claim 62.

C. Second Paragraph

Claims 9-17, 29-32, 34-38, 52-55, 57, 62-63, 67-69, and 78-84 were rejected for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. *See* Office Action, pp. 6-8. The Office Action asserted, "The hydrogel in the generic claims is an amount of about 0.5% to 25% of the total weight of the hydrogel and it is confusing how the 'hydrogel' is of a certain amount of the 'hydrogel.'" *See id.* In addition, the Office Action also asserted that the claims do not recite a specific site of administration/injection. *See id.*

Applicant respectfully submits that the amended claims overcome the rejection. First, independent claims 9, 78-80, and 85, from which all other pending claims depend, have been amended to clarify that the hydrogel comprises about 0.5% to 25% of a polymer, based on the total weight of the hydrogel. Second, claims 9, 78-80, and 85 all recite "urethra" or "urethral," as discuss in Section III(B). For at least these reasons, Applicant respectfully requests that the rejection be reconsidered and withdrawn.

IV. Rejection Under 35 U.S.C. § 103

The examiner bears the initial burden of establishing a *prima facie* case of obviousness. If the examiner does not satisfy his/her burden, then the applicant is not obligated to submit evidence of nonobviousness. *See* M.P.E.P. § 2142.

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

See id.

A. Pavlyk in View of Sknar and Further in View of Applicant's Admission

Claims 9-15, 29-31, 34-36, 52-54, 62, 63, 67-69 and 78-84 were rejected for being unpatentable over U.S. Patent No. 5,798,096, in issued to Pavlyk ("Pavlyk"), in view of Russian Application No. 2148957, in the name of Sknar, *et al.* ("Sknar"), and further in view of Applicant's admission in an Examiner interview held on February 23, 2006 and in a Response

filed February 27, 2006 ("Applicant's Admission"). *See* Office Action, pp. 8-11. Applicant respectfully traverses the rejection.

Pavlyk describes a polyacrylamide hydrogel comprising 3.5% to 9.0% cross-linked polyacrylamide for cosmetic procedures, such as for bulking of the penis, rectomammarily for bulking of breasts, and for filling in wrinkles. In addition, Pavlyk clearly teaches that "[c]oncentrations below 3.5% make the hydrogel unstable . . . while concentrations above 6.0% decrease fluidity of the hydrogel practically to zero and is practicable in manufacturing firm, form-retaining, precast endoprosthesis." Col. 3, ll. 46-52. Moreover, in the procedures described in Pavlyk, the prosthetic device performs no physiological/biological function. Even more specifically, there is no teaching to use a polyacrylamide hydrogel for treating urinary incontinence by urethral bulking.

Sknar discloses the administration of "Interfall" polyacrylamide gel, which is a gel within the scope disclosed by Pavlyk, into the ostium of the ureter for the treatment of vesicouretal reflux ("VUR"). Sknar, however, is not directed to the treatment of urinary incontinence. VUR and urinary incontinence are unrelated, both clinically and anatomically. VUR is a reflux from the "top" of the bladder back up through the ureter(s) to one or both of the kidneys, which may cause severe kidney infections. A normal, healthy flow of urine begins at the metabolic processes of the kidneys, and then passively flows or drips down from each of the kidneys through each of the ureters into the bladder. Sknar describes a relatively passive role of the gel, whereby the gel "plugs" the ureter to non-therapeutically, but non-intrusively, partially impede the normal passive flow of urine from the kidney down through the ureter and then to the bladder. Due to its positioning at the mouth between the ureter and the bladder, the gel plays its passive therapeutic role to prevent the reflux of urine from the top of the bladder and up the ureter.

By contrast, the present invention allows for the treatment of urinary incontinence by bulking the urethra, which is found at the lower end of the bladder. Therefore, the urethra is at the opposite end of the bladder from the ureter, the later being the focus of the treatment for VUR, whereas the former being the focus of the present invention. Specifically, the ureters lead from the kidneys to the bladder whereas the urethra leads out from the bladder to empty the bladder in the active process of urination. In urinary incontinence, the voluntary muscles (sphincters) of the urethra have weakened to the point of being ineffective and/or the urethra has

lost its internal shape, folds, and ridging, often due to age. The active processes of urination and urine retention are no longer under the voluntary control of the sufferer.

Sknar describes the treatment of VUR in Example 1; however in the Example, a child diagnosed with VUR and pyelonephritis (inflammation of the kidneys, pelvis, and calices) also complained of urinary incontinence. The child was treated for VUR by injecting the gel into the ureter. Months later, the child had "no complaints." Although VUR is unrelated clinically and anatomically to urinary incontinence, the treatment of VUR by injecting the gel into the ureter seemed to alleviate urinary incontinence in the child. The most plausible explanation for this observation is that the incontinence was due to the infected and irritated bladder caused by the VUR. The irritated bladder must have then lead to incontinence. One or ordinary skill in the art would recognize that injections into the ureter are not a means for treating urinary incontinence. Moreover, there is no teaching in Sknar to treat urinary incontinence by bulking the urethra with the polyacrylamide hydrogel.

Although Sknar teaches the use of a gel within the disclosure of Pavlyk for the treatment of VUR, the combined teachings of Pavlyk and Sknar still do not provide any motivation or suggestion to carry out urethral bulking by using the polyacrylamide hydrogel. First, from a practical and medical point of view, given the "passive" versus "active" functions of the ureter compared to the urethra, the treatment of urinary incontinence is of a far higher degree of complexity than the treatment of VUR. Contrary to the ureter, the urethra is involved in both the voluntary retention of urination and in the voluntary urination whereas the ureter is involved in only the involuntary, passive flow of urine into the bladder. The musculature in the urethra involved in voluntarily retaining urine and voluntarily urinating is subtle, yet significant. The complexity of the control of this musculature under stress and urge is likened to keeping one's balance on a bicycle: it is difficult to learn for children and often lost in the elderly. This complexity is not found in the passive function of the ureter. A material used for urethral bulking must be able to 1) functionally adapt as the muscles of the urethra contract and relax, 2) fill the lost or deformed folds within the urethra, and 3) provide resistance by bulking. Of equal importance to retaining urine in the treatment of urinary incontinence is the need to allow for voluntary urination. Therefore, the material used for the treatment of urinary incontinence must provide a sufficient balance of elasticity and viscosity. Because these requirements are not found in the material used for the treatment of VUR, one of ordinary skill in the art would not

reasonably expect to successfully use a material for the treatment of VUR as the material for the treatment of urinary incontinence.

Second, the combined teachings of Pavlyk and Sknar do not teach or suggest each of the claimed limitations. The present invention requires either bulking of the urethra, injecting the hydrogel in the urethra, or increasing resistance of passage through the urethra, none of which are disclosed in Pavlyk or Sknar.

For at least the aforementioned reasons, the *prima facie* case of obviousness has not been established. Therefore, the combination of Pavlyk and Sknar do not render the present invention obvious under 35 U.S.C. § 103. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

B. Vogel in View of Sknar and Further in View of Applicant's Admission

Claims 9-17, 29-32, 34-38, 52-55, 57, 62, 63, 67-69 and 78-84 were rejected for being unpatentable over U.S. Patent No. 6,335,028, in issued to Vogel ("Vogel"), in view Sknar and further in view of Applicant's Admission. *See* Office Action, pp. 11-12. Applicant respectfully traverses the rejection.

Applicant initially points out that an obviousness rejection over Vogel was previously raised during prosecution. *See e.g.*, final Office Action dated October 14, 2004, pp. 3-5. However, after holding an examiner interview and submitting an Amendment in response to the October 14, 2004 Office Action, the rejection was withdrawn. *See* Advisory Action dated December 29, 2004, p. 2.

As described in the Statement of Substance of Interview and Amendment filed on December 14, 2004, Vogel discloses solid microparticles that maintain their shape when implanted and a liquid suspension of the microparticles. *See* Vogel, col. 6, ll. 20-23 and 52-55. The present invention, on the other hand, is directed to a pliable hydrogel that takes the shape of the cavity in which it is administered. This property of the hydrogel is recited in the claim as a complex viscosity of about 2 to 50 Pas, which provides for a colloidal solution. While Vogel does not disclose the complex viscosity of the solid microparticles described therein, the complex viscosity of the microparticles would likely be significantly greater than 50 Pas due to their solid state. Moreover the liquid suspension for injection, which comprises the microparticles, would not have a *complex* viscosity. Instead, it would only have a viscosity due to its fluid nature. Although the prosthetic device of the present invention does not exclude a

hydrogel suspended in a liquid, the claim recites that the hydrogel, not the prosthetic device, has a complex viscosity of 2 to 50 Pas. Therefore, Vogel does not teach or suggest each of the claim limitations.

The combination of Vogel and Sknar also does not teach or suggest each of the claim limitations. The hydrogel disclosed in Sknar, and as described in Section IV(A) above, does not provide for the missing claim limitation in Vogel, namely complex viscosity. Furthermore, one of ordinary skill in the art would not be motivated to use the hydrogel disclosed in Sknar for the urinary incontinence treatment of Vogel because of the difference in the passive function of the ureter and active function of the urethra, as discussed above. Finally, even if one of ordinary skill in the art were to combine Sknar and Vogel, he/she would not have a reasonable expectation of success due to the vast difference in using the solid microparticles of Vogel for the treatment of urinary incontinence, which is an "active" function, and using the gel of Sknar for the treatment of VUR, which is a "passive" function.

For at least the aforementioned reasons, the *prima facie* case of obviousness has not been established. Therefore, the combination of Vogel and Sknar do not render the present invention obvious under 35 U.S.C. § 103. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

V. Request for Examiner Interview

For at least the reasons stated above, the rejections have been properly traversed, accommodated or rendered moot. Thus, Applicant respectfully submits that claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80, and 82-90 are in condition for allowance. Accordingly, Applicant respectfully requests that the Application be allowed and passed to issue.

In the event any outstanding issues remain and the Examiner determines the claim are not in condition for allowance, Applicant hereby requests a personal Examiner Interview. Applicant would appreciate the courtesy of a telephone call to Applicant's representative to schedule the interview.

CONCLUSION

It is believed that no additional fees are due in connection with this Amendment. However, in the event it is determined by the USPTO that a variance exists between the amount due and the amount authorized above, the Commissioner is hereby authorized to debit or credit any such variance to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,
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Date: May 24, 2007

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